



MCW Office of Research Standard Operating Procedure

REQUIREMENTS & QUALIFICATIONS TO SERVE AS A PRINCIPAL INVESTIGATOR

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

To define and explain the requirements and qualifications of persons who assume the role of Investigator of a human subject research project.

DEFINITIONS:

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

Definition of Investigator

The MCW IRB defines Principal Investigator (PI) as anyone who engages in the following:

1. any individual who leads or directs a research project involving human subjects
2. any individual who performs activities that engage MCW/FH in anyone else's research project
3. any individual that uses MCW/FH resources; including lab equipment, physical space, or services
4. any individual who brings research data onto the campus
5. any individual who performs any research activity on MCW/FH campus

A PI has overall responsibility for the conduct of a research project, including all technical, programmatic, financial, compliance, and administrative aspects. The PI is responsible for controlling the technical direction and academic quality of the project, and will ensure that the project is carried out in compliance with the terms, conditions, and policies of the institution and sponsor, when applicable.

Office for Human Research Protections (OHRP) - For the purposes of the HHS regulations, OHRP defines investigator as any individual who is involved in conducting human subject research studies. Such involvement would include:

1. obtaining information about living individuals by intervening or interacting with them for research purposes;
2. obtaining identifiable private information about living individuals for research purposes;
3. obtaining the voluntary informed consent of individuals to be subjects in research; and
4. studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research projects are conducted by more than one investigator, and usually one investigator is designated the "principal investigator" with

overall responsibilities for the project. In every human subject research project, investigators have certain responsibilities regarding the ethical treatment of human subjects. (45 CFR 46)

Food and Drug Administration (FDA) – The FDA defines investigator as an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. (21 CFR 50.3 (d))

POLICY:

1. MCW currently recognizes the following classes of individuals that are eligible to work as a PI at MCW. Residents and fellows may not serve as the PI on projects. They may be co-Investigators collaborating with an eligible MCW PI.
 - a. **Faculty Paid:** Pursuant to the rules of the Faculty Handbook, individuals with a faculty appointment are eligible to serve as investigators at MCW. The individuals in this classification are employees of MCW. The coordination of their faculty appointment and research is handled through the academic department through which they are appointed.
 - b. **Faculty Unpaid:** Pursuant to the rules of the Faculty Handbook, individuals with an unpaid adjunct or voluntary clinical appointment are eligible to serve as investigators at MCW. However, because these individuals are not employees of MCW, there are some additional administrative steps which must be followed related to their appointment and research work at MCW. Individuals with this designation may receive their appointment and primary research support either through an academic department or through the Clinical & Translational Science Institute (CTSI).
 - c. **CTSI Scientist or CTSI Senior Scientist:** This designation was specifically created for individuals without a terminal degree who do not meet the eligibility criteria to become faculty at MCW, but whom MCW has determined can provide value in conducting research on our campus. Individuals in this category must receive their appointment through the CTSI office and seek administrative research support from them as well.
 - d. **Froedtert Hospital Nurses:** This designation was specifically created for individuals with a nursing degree who do not meet the eligibility criteria to become faculty at MCW, but whom FH has determined can provide value in conducting research on the MCW/FH campus. Individuals in this category must receive designation from the Froedtert Nursing Research Council, a Ph.D. nurse researcher, and the Chief Nursing Officer.
 - e. **Froedtert Hospital Pharmacists:** This designation was specifically created for individuals with a pharmacist degree who do not meet the eligibility criteria to become faculty at MCW, but whom FH has determined can provide value in conducting research on the MCW/FH campus. Individuals in this category must receive designation from the Froedtert Pharmacy Research and Professional Development Committee.
 - f. **Community Memorial Hospital (Menomonee Falls)** This designation was specifically created for individuals from Community Memorial Hospital in Menomonee Falls who are not MCW faculty, but for whom FH has determined can provide value in conducting research at Community Memorial Hospital. Individuals in this category must be a physician, hold a medical appointment at Community Memorial Hospital, and receive special designation from FH Corporate Compliance.
 - g. **St. Joseph's Hospital (West Bend) Physicians:** This designation was specifically created for individuals from St. Joseph's Hospital who are not MCW faculty, but whom FH has determined can provide value in conducting research

at St. Joseph's Hospital. Individuals in this category must be a physician, hold a medical appointment at St. Joseph's Hospital-West Bend, and receive designation from FH Corporate Compliance.

- h. **Blood Center of Wisconsin (BCW) Investigators:** This designation was specifically created for individuals from Blood Center of Wisconsin who are not MCW faculty, but for whom BCW has determined can provide value in conducting research at BCW. Individuals in this category must be BloodCenter staff with a Master's degree or higher. Fellows may not be the PI on research projects. They may be co-Investigators collaborating with an eligible PI as identified per this policy.

2. Questions regarding eligibility to conduct research studies involving human subjects should be directed to the MCW HRPP Office.

Appointment review and approval process

There are three distinct review and approval processes: one for individuals receiving appointments through academic departments, one for those appointed through the CTSI, and a one for those appointed through the Froedtert Nursing Leadership Committee.

Institutional Review Boards (IRBs)

1. MCW faculty work at a variety of inter-related but separate institutions, and many of these institutions have their own IRBs.
2. The MCW Human Research Protection Program (HRPP) office recommends that Investigators contact the IRB that has appropriate jurisdiction before preparing an application as each IRB has its own application process and policies.
3. If the Investigator is aware of multiple institutions being involved with a project, they should contact the IRB to determine if multiple reviews can be avoided through the set up and execution of an Inter-institutional Authorization Agreement (IAA). For more information about multiple site projects and IAAs refer to *IRB SOP: Reliance Agreements for Multi-Site Projects*

Institutional Human Subject Research Educational Requirements

All Investigators engaged in the conduct of human subject research under the oversight of MCW IRB must complete required human subjects research protections training prior to submission of a research project for review and approval to the MCW IRB.

Investigators are required to remain up-to-date with required trainings to continue to conduct research as outlined in the *IRB SOP: Human Subject Research Protections Training Requirements*.

REFERENCES:

- 45 CFR 46
- 21 CFR 50.3 (d)

SUPPORTING DOCUMENTS:

IRB SOP: Reliance Agreements for Multi-Site Projects

IRB SOP: Human Subject Research Protections Training Requirements

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Approved By
HRPP Authorized Official: David Clark, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin